

REMARKS

I. Status of the Application.

Claims 1-17, 41, and 42 are currently pending in this Application. In this Response, Applicants have canceled claims 3, 13-15, and 41-42, amended claims 1-2, 4-7, 12, and 16-17, and added claims 43-47. In view of the foregoing amendments and for the reasons set forth below, Applicants respectfully submit that the rejection of claims 1-17, 41 and 42 should be withdrawn and this Application should proceed to allowance.

II. No New Matter Is Introduced by Way of Amendment.

Applicants submit that amended claims 1-2, 4-7, 12 and 16-17 and new claims 43-47 do not introduce new matter. Support for these amended and new claims is provided, for example, in Figures 1-4 and on pages 7-13. Accordingly, Applicants respectfully request that the amended and new claims be accepted and entered.

III. The Rejection of Claims 1-5, 13-17, 41, and 42 Under 35 U.S.C. §102(b) As Being Anticipated By U.S. Patent No. 6,062,224 To Kissinger et al. ("Kissinger") Is Overcome And Should Be Withdrawn.

Applicants respectfully submit that the rejection of claims 1-5, 13-17, and 41-42 should be withdrawn because claims 3, 13-15 and 41-42 have been canceled and Kissinger does not disclose all of the limitations of amended claim 1. A rejection under 102(b) can be overcome by showing that the prior art does not disclose all the limitations of the claims. MPEP §706.02(b). Applicants respectfully submit that Kissinger, among other things, does not disclose a drug delivery system that comprises "at least a first and a second fluid reservoir, wherein each of the fluid reservoirs contains a fluid and wherein the first fluid reservoir is attached to one of the at

least two syringes by one of the plurality of disposable tubes and wherein the second fluid reservoir is attached to another of the at least two syringes by one of the plurality of disposable tubes," as claimed in amended claim 1. Kissinger only discloses a syringe pump that can be operated to withdraw blood samples through a tube manifold and a single reservoir filled with saline that can be used to flush the tube system catheter. (Fig. 12, Cols. 20-23). Accordingly, Applicants respectfully submit that the rejection of claim 1 under 35 U.S.C. §102(b) as being anticipated by Kissinger should be withdrawn because Kissinger does not disclose all the limitations of amended claim 1. Moreover, Applicants respectfully submit that the rejection of pending claims 2, 4-5, and 16-17 should be withdrawn because each of these claims depend from and incorporate all of the limitations of amended claim 1.

IV. The Rejection of Claims 1-3, 14, 15, 41, and 42 Under 35 U.S.C. § 103(a) as Unpatentable Over U.S. Patent No. 6,767,319 To Reilly et al. ("Reilly") In View Of U.S. Patent No. 6,187,529 To Fahy et al. ("Fahy") Is Overcome And Should Be Withdrawn.

Applicants respectfully submit that the rejection of claims 1-3, 14, 15, and 41-42 as being obvious over Reilly in view of Fahy should be withdrawn because claims 3, 14-15, and 41-42 have been canceled and the Examiner fails to establish a *prima facie* case of obviousness for claims 1-2 based on Reilly and Fahy. Three criteria must be met to establish a *prima facie* case of obviousness: (i) there must be some suggestion or motivation to combine the teachings of two or more prior art references; (ii) there must be a reasonable expectation of success; and (iii) "all of the claim limitations must be taught or suggested by the prior art." MPEP §§ 2143 and 2143.03 (citing *In re Royka*, 490 F.2d 981 (C.C.P.A. 1974)).

A. No Suggestion Or Motivation Exists To Combine Reilly With Fahy.

Applicants respectfully submit that there is no suggestion or motivation to combine Reilly with Fahy in order to replace the stopcock valves of Reilly's device with the pinch valve located in Fahy's double cylinder reservoir. The Examiner alleges that "it would have been obvious for one of ordinary skill in the art to combine the system of Reilly et al. with Fahy et al. because Fahy et al. discloses the benefit of using a pinch type valve, which is the easy removal of the valve from the tubing." (Office Action, p.3). Applicants respectfully submit that this motivation would not lead one of ordinary skill in the art to combine Reilly with Fahy, because Reilly discloses a device for the delivery of a hazardous pharmaceutical that has a primary purpose of minimizing or eliminating the exposure of the operating personnel to such hazardous material. (Col. 8, ll. 34-55). Thus, one skilled in the art would not replace the stopcock valves of the Reilly device with the pinch valve from Fahy for "the benefit . . . (of) easy removal of the valve from the tubing", because the ability to remove is not a desired benefit for the Reilly device. Removal of the valve from the tubing would cause a user to be exposed to the hazardous pharmaceutical. Such exposure is in direct contrast to the purpose of the Reilly device, which is to protect operating personnel from exposure to the hazardous pharmaceutical. If anything, such a teaching of use of a pinch valve for the purpose of easily removing the valve from the tubing teaches away from the combination of Reilly with Fahy, because one of ordinary skill in the art would not want to use anything that would permit the user to remove any portion of the Reilly device. Such removal would cause exposure to the hazardous pharmaceutical, which is what the Reilly device is trying to prevent. Accordingly, Applicants respectfully submit that no motivation

or suggestion exists to combine these references, because the Examiner's stated motivation would be in direct contrast to Reilly's stated purpose of minimizing or eliminating exposure to the hazardous pharmaceutical.

In maintaining the rejection of obviousness based on Reilly in view of Fahy, the Examiner alleged that "it would be obvious to switch the stopcock valve with a pinch valve since one of ordinary skill in the art would be able to use different valve [sic] depending on the type of circumstance and intended use of the invention." (Office Action, p. 4). This statement does not rely on the references themselves but impermissibly relies on the skill of one of ordinary skill of the art. As stated in the MPEP, "[t]he level of skill in the art cannot be relied upon to provide the suggestion to combine references." MPEP § 2143.01 (citing *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999). Rather, "[o]bviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention *where there is some teaching, suggestion, or motivation to do so.*" *Id.* (citing *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006)). As explained above, Applicants respectfully submit that there is no teaching, suggestion or motivation to combine these references because one of ordinary skill in the art would not desire to allow a user of the Reilly device to easily remove a valve in view of the fact that such removal would cause the user to be exposed to the hazardous material.

B. The Combination Of Reilly With Fahy Does Not Teach Or Suggest All Of The Limitations Of Claims 1-3, 14 and 15.

Irrespective of the lack of motivation or a suggestion to combine the references, Applicants respectfully submit that the combination of Reilly with Fahy does not teach or

suggest all of the limitations of claim 1. Specifically, the combination of these references do not teach or suggest "at least one pinch valve, each pinch valve having a first position and a second position, wherein the second position receives one of the plurality of disposable tubes therethrough at a position located between the at least one catheter and one of the at least two syringes," as claimed in claim 1.

While Reilly discloses the use of stopcock valves throughout its system, a combination of Reilly with Fahy would not yield a drug delivery device comprising "at least one pinch valve . . . at a position located between the at least one catheter and one of the at least two syringes", as claimed in claim 1. Rather, the combination of Fahy with Reilly would yield a device that would use a pinch valve to control flow from the outer cylinder to the inner cylinder of the reservoir and would still use stopcock valves for the rest of the Reilly system. Fahy specifically teaches that the pinch-type valve is preferable for fluid control between such reservoir cylinders because of the small pressure difference available to drive fluid flow and the need for a large working diameter fluid path. (Fahy, Col. 17, ll. 21-29). Aside from the reservoir, the rest of Fahy and the entire device of Reilly uses pressure (i.e., use of syringes and pumps) to drive the fluid. In each case, where fluid is driven by pressure, Fahy and Reilly utilize valves in fluid connection (i.e., stopcock/solenoid valves) with the tubes to control the flow of fluid in the respective systems. Neither Fahy nor Reilly contemplate, disclose, teach or suggest the use of a pinch valve in any other position than Fahy's double cylinder reservoir. Thus, a combination of these references yields only a fluid system with a two cylinder reservoir that uses a pinch valve to control the flow of fluid between the cylinders, while the rest of the tubing is in fluid communication with a

series of solenoid/stopcock valves. Such a combination does not disclose, teach or suggest a drug delivery device comprising "at least one pinch valve . . . at a position located between the at least one catheter and one of the at least two syringes", as claimed in claim 1.

C. Applicants Respectfully Request That The 35 U.S.C. §103(a) Rejections Be Withdrawn.

For all of the above reasons, Applicants respectfully submit that claim 1 is not obvious under 35 U.S.C. §103(a) over Reilly in view of Fahy and requests that these rejections be withdrawn. Moreover, Applicants respectfully submit that claim 2 is also not obvious over Reilly in view of Fahy because this claim depends from claim 1. "If an independent claim is not obvious under 35 U.S.C. §103, then any claim depending therefrom is not obvious." MPEP § 2143.03 (citing *In re Fine*, 837 F.2d 1382, 1385 (C.C.P.A. 1970)). For the foregoing reasons, Applicants respectfully request that the rejections of claims 1-3, 14, 15, and 41-42 under 35 U.S.C. §103(a) be withdrawn and that the Application proceed to allowance.

V. The Rejection of Claims 4-13, And 16-17 Under 35 U.S.C. § 103(a) as Unpatentable Over Reilly In View Of Fahy As Applied To Claims 1-3, 14 And 15 And In Further View Of U.S. Patent No. 5,609,572 to Lang ("Lang") Is Overcome And Should Be Withdrawn.

Applicants respectfully submit that the rejections of claims 4-13 and 16-17 under 35 U.S.C. §103(a) are now moot and should be withdrawn because claim 13 has been canceled and the rest of the claims each depend from claim 1, which as discussed above, is not obvious over Reilly in view of Fahy. "If an independent claim is not obvious under 35 U.S.C. §103, then any claim depending therefrom is not obvious." MPEP 2143.03 (citing *In re Fine*, 837 F.2d 1382, 1385 (C.C.P.A. 1970)).

VI. Claims 43-47 Are In Allowable Form.

Applicants respectfully submit that new claims 43-47 are in allowable form, supported by the specification, and do not constitute new matter. Accordingly, Applicants respectfully submit that claims 43-47 should be accepted and allowed.

VII. Applicants Petition for an Extension of Time.

Applicants hereby petition for an extension of time of two (2) months, under 37 C.F.R. § 1.136(a), thereby extending the deadline for response, pursuant to 37 C.F.R. §§ 1.7(a) & 1.136(a), to Monday, April 2, 2007. Applicants authorize payment for this extension of time in the amount of \$225.00 to be charged to the identified credit card. When doing so, please reference the above-listed docket number for this file.

CONCLUSION

For all the foregoing reasons, it is respectfully submitted that the Applicants have made a patentable contribution to the art and that this response places the above-identified application in condition for allowance. Favorable reconsideration and allowance of this application is respectfully requested.

Commissioner for Patents
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In the event the Applicants have inadvertently overlooked the need for an extension of time or payment of an additional fee, the Applicants conditionally petition therefor, and authorize any fee deficiency to be charged to deposit account 09-0007.

Sincerely,

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